K082910
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510(k) SUMMARY
(as required by 807.92(c))

JUN 17 2009

Regulatory Correspondent:

Jon Ward
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Apollo Beach, FL 33572
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Submitter of 510(k):

ASO LLC
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Sarasota, FL 34240
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Contact Person: Joan Rubendall

Date of Summary: 6/1/09

Classification Name: Dressing, Wound, Drug

Product Code: FRO

Trade/Proprietary Name: Multiple –Bandages shall be marketed as private label brands identified with the customer's name or trade name.

Device Description:

There will be two primary models covered under this submission, the Silver Bandage which will be available by prescription only and the Bandage which will be available for over-the-counter use.

Silver Bandage is an adhesive bandage that includes silver in the wound pad. The bandage covers the wound area. The Silver Bandage may be used under supervision of a healthcare professional. In Vitro testing showed that silver in the pad reduced bacterial growth by over 99% (S. aureus, S. aureus(MRSA), E. coli, E. hirae and P. aeruginosa) for 24 hours contact time.

	The Bandage is an adhesive bandage which may be purchased for over-the-counter use as a first aid. The device consists of a hydrophyillic pad stock with sufficient absorbency to absorb normal quantities of blood or other wound exudates typical of minor abrasions or lacerations, supplied on a flexible, non-absorbent backing coated with a pressure sensitive adhesive capable of adhering the device to human skin
Intended Use:	Prescription Use - Under the supervision of a healthcare professional, Silver Bandages are indicated for the management of pressure ulcers diabetic foot ulcers, as well as minor cuts, scrapes, abrasions, lacerations, and burns. Over-the-counter Use - The Bandages are indicated for first aid to cover minor cuts, scrapes, abrasions, lacerations and burns.
Technological Characteristics:	The both bandages have a traditional bandage design consisting of an adhesive coated backing, wound pad that contains silver, paper release tabs and protected by a cohesive coated paper wrapper that serves as the sterile barrier. The types of materials are similar to the Curad ® Silver Bandage with silver. Equivalent concentrations of silver are released in the predicate device and new device. Biocompatibility assessment was performed on the bandage to include patient skin contact surface (tape) and the fluid path contacting surface (the silver pad) with satisfactory results.
Performance Testing:	In Vitro testing showed that silver in the pad, of the prescription use Silver Bandages, reduced bacterial growth by over 99% (S. aureus, S. aureus(MRSA), E. coli, E. hirae and P. aeruginosa) for 24 hours contact time.
Substantial Equivalence:	Both bandage products (Prescription and OTC) products are substantially equivalent in design and function to the Curad® Silver Bandage manufactured by Beiersdorf, Inc. The Curad® Silver Bandage was cleared by FDA under K032463.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2009

ASO LLC
% AJW Technology Consultants, Incorporated
Mr. Jonathan Ward
962 Allegro Lane
Apollo Beach, Florida 33572

Re: K082910
Trade/Device Name: Silver Bandage
Regulation Number: Unclassified
Regulation Name: Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 2, 2009
Received: June 3, 2009

Dear Mr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing

practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082910

Device Name: Silver Bandage

Indications for Use:

Under the supervision of a healthcare professional, Silver Bandages are indicated for the management of pressure ulcers diabetic foot ulcers, minor cuts, scrapes, abrasions, lacerations, and burns.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K082910

Indications for Use

510(k) Number (if known): K082910

Device Name: Bandages

Indications for Use:

The Bandages are indicated for first aid to cover minor cuts, scrapes, abrasions, lacerations and burns.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for M&M

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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